

EXHIBIT F

0271

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 IN RE: ETHICON, INC. : MDL NO. 2327
5 PELVIC REPAIR SYSTEM, :
6 PRODUCTS LIABILITY :
7 LITIGATION :

8 - - -
9 - - -
10 July 20, 2013
11 VOLUME II
12 - - -
13 THIS DOCUMENT RELATES TO ALL CASES

14 - - -
15 July 20, 2013
16 VOLUME II
17 - - -
18 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

19 Continued videotaped deposition of
20 AXEL ARNAUD, MD taken pursuant to notice, was held
21 at the law offices of Riker Danzig Scherer Hyland &
22 Perretti LLP, Headquarters Plaza, One Speedwell
23 Avenue, Morristown, New Jersey, beginning at 9:08 a.m.,
24 on the above date, before Ann Marie Mitchell, a
25 Federally Approved Certified Realtime Reporter,
26 Registered Diplomate Reporter and Notary Public for
27 the State of New Jersey.

28 - - -
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2 I N D E X
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5 Testimony of: AXEL ARNAUD, MD
6 By Mr. Slater 282
By Mr. Cartmell 442
7

[446:23] - [447:1]

page 446

23 Q. I see.
24 Now, you mentioned Ulmsten. Prof.
25 Ulmsten is the inventor of this device?

page 447

1 A. Yes.

[449:23] - [453:24]

page 449

20 Q. And he contacted you in September of
21 1995 it says; is that right?

22 A. Yes, yes.

23 Q. Now, at that time -- and I'm going to
24 paraphrase through this, so correct me if I'm wrong
25 at any time, but it sounds like at that time he was

page 450

1 contacting you to see if you would be interested in
2 talking to the inventor of what became the TVT
3 device, Prof. Ulmsten. Right?

4 A. Yes.

5 Q. Prof. Ulmsten apparently at this time
6 in 1995 was looking to talk to a company about what?

7 A. Well, you know, when a doctor invent
8 a procedure, he knows that if there is not a company
9 that takes care of the promotion to let the world
10 know about the procedure, very likely this procedure
11 is going to remain in -- somewhat confidential, you
12 know, maybe widespread around his hospital, a couple
13 of friends, but it's -- unlikely it's going to
14 become something that change the rule of the game.
15 So that was the main reason why Ulmsten was looking
16 for a company.

17 Q. Was he interested in potentially
18 having Ethicon partner up with him to purchase his
19 invention or to help him sell his invention in some
20 way?

21 MS. JONES: Object to the form.

22 THE WITNESS: Not really. You know,
23 I think it was essentially driven by letting the
24 world know about his procedure.

25 BY MR. CARTMELL:

page 451

1 Q. I see.
2 But did he have a patent at that
3 time?

4 A. Well, Ulmsten personally did not have
5 a patent, because he had the -- two -- one or two
6 patent have been filed, and they were filed I think
7 by a company called Medscand, which, of course, are
8 very close from Ulmsten, but Ulmsten, you know, was
9 not -- he was just a doctor, and he had a friend of
10 him who was the head of Medscand, the company that
11 was making medical devices. So he worked with
12 Medscand, and Medscand took care of the patents, so
13 he is probably the inventor, but Medscand might be
14 the owner of the patents. You know, I don't
15 remember exactly the details.

16 Q. A few things that I want to follow up
17 on what you just said.

18 You mentioned that Prof. Ulmsten is a
19 doctor. He was a Swedish surgeon. Right? Is that
20 right?

21 A. Yes.
 22 Q. And this company, Medscand, you
 23 mentioned that it was -- or at the time it was a
 24 medical device company. What types of medical
 25 devices was that company selling?
 page 452
 1 A. Well, they were selling, and I think
 2 they were the number one in the world, a very small
 3 device for uterine sampling, you know, to sample
 4 cells in the uterine cavity. Something like that.
 5 You know, very -- they did not have a broad
 6 portfolio, just I think one product or two, but this
 7 one was a good product because it was I think the
 8 number one product in the world.
 9 Q. What type of device was that,
 10 uterine?
 11 A. Uterine sampling, you know, when you
 12 perform a gynecologic examination and you put
 13 something in the uterus to sample and take some
 14 cells to look if there is no cancer cells.
 15 Q. I see.
 16 And you mentioned that Mr. Ulmsten's
 17 good friend was actually one of the owners of that
 18 company; is that right?
 19 A. Yes.
 20 Q. And I think based on the documents
 21 we've seen, Prof. Ulmsten was also a shareholder or
 22 part owner in that company as well; is that right?
 23 A. Well, to my best knowledge, because I
 24 missed one part which was the deal. Ulmsten was not
 25 a shareholder at the beginning, but when we signed
 page 453
 1 this deal with the company, I believe his friend who
 2 was owning the company wanted to reward him and
 3 probably gave him shares of the company. But I
 4 don't think he was initially, you know, a
 5 stakeholder -- a stockholder of the company.
 6 Q. And we'll talk about -- you mentioned
 7 the part of your history of the TVT related to the
 8 deal in a minute. But let's move forward and talk
 9 about -- you state here in the second paragraph here
 10 that you had a visit to Uppsala in November of 1995.
 11 And that, when you say you went to
 12 Uppsala, what is Uppsala?
 13 A. Uppsala is a city nearby Stockholm
 14 where -- which is a university city where Ulmsten
 15 was working.
 16 Q. Dr. Ulmsten had actually sent a
 17 video, or your contemporary, Mr. Harm, had sent you
 18 a video of this surgery that Prof. Ulmsten had
 19 invented as far as the technique; is that right?
 20 A. Yeah. It was a video of the surgical
 21 procedure, but there was some comments,
 22 unfortunately, in Swedish. So it was not very easy
 23 for me to understand what this guy was exactly
 24 doing.
 25 Q. So did you decide to go and actually
 page 454
 1 view the surgery live?
 2 A. Yes.

[454:24] - [461:5]

page 454
 21 But first, I was just asking if
 22 that's correctly what you stated at that time?
 23 A. Yes, yes.
 24 Q. Now, when you went and you viewed the
 25 surgery that was performed by Prof. Ulmsten, was the

page 455

1 product that Prof. Ulmsten was using in November of
2 1995 a prototype of what has become the current TVT
3 device?

4 A. Yeah. It was very close to what will
5 be the TVT.

6 Q. Let's go to page 2, if you don't
7 mind, and under paragraph 4 where you talk about
8 your "Visit to Somerville." In the third paragraph
9 you make a statement, "I planned a trip to
10 Somerville. The key problem I faced was deciding
11 whether this project fell under the R&D or the New
12 Business VP responsibility." And I want to ask you
13 about the next sentence.

14 "Indeed, in order to get prototypes
15 for clinical use, Pr. Ulmsten had relied upon a
16 small Swedish company (Medscand A.B.), whose CEO was
17 a good friend of him. Medscand had also applied for
18 a patent."

19 And we talked about that. Medscand
20 was the company owned by Prof. Ulmsten's good friend
21 that he was actually working with at that time.
22 Correct?

23 A. Yes.

24 Q. And it mentions that this was a
25 prototype device at the time.

page 456

1 And was Medscand providing any part
2 of the prototype device at this time?

3 A. Well, at this time, Medscand was
4 manufacturing this device Ulmsten used in his first
5 patients, you know, before I met him.

6 Q. And when you say it was -- Medscand
7 was manufacturing the device, was the device made up
8 of -- like the TVT device today, needles?

9 A. Yes, yes.

10 Q. And also mesh. Right?

11 A. Well, I would not say exactly, but
12 very -- 90 percent -- 99 percent similar.

13 Q. I want to hand you Exhibit T-879.

14 - - -

15 (Deposition Exhibit No. T-879,
16 Article entitled "An Ambulatory Surgical
17 Procedure Under Local Anesthesia for
18 Treatment of Female Urinary Incontinence"
19 by U. Ulmsten, et al., Bates stamped
20 ETH.MESH.05795664 through
21 ETH.MESH.05795669, was marked for
22 identification.)
23 - - -

24 BY MR. CARTMELL:

25 Q. Dr. Arnaud, this is an article from

page 457

1 1996, and the lead author of this article, as you
2 can see, is Prof. Ulmsten; is that right?

3 A. Yes, yes.

4 Q. This is actually, it states, an
5 "Original Article."

6 Is this the original article that
7 Prof. Ulmsten wrote related to the prototype device
8 and the technique he was using to treat stress
9 urinary incontinence as of 1996?

10 A. Yes, yes.

11 Q. If you turn to the second page of
12 this article, it's got the page number 78 in the
13 lower right-hand corner, there is a picture,
14 actually, I believe of the prototype device that Dr.
15 Ulmsten was using as of this time in 1996. Right?

16 A. Yes.

17 Q. And similar looking to actually what
18 became the TVT and sold by Ethicon. Right?

19 A. Yes.
20 Q. The paragraph just above the picture
21 states, "The instrument (Medscand AB, Johnson &
22 Johnson, Sweden)," and then it refers down to the
23 picture; is that right?

24 A. Yes.
25 Q. Now, at this time, did Johnson &

page 458

1 Johnson -- strike that.
2 What is Johnson & Johnson Sweden?
3 A. Well, at that time, Johnson & Johnson
4 had headquarters for Sweden -- Scandinavia probably
5 in Sweden.

6 Q. So there was actually an entity, a
7 corporation, called Johnson & Johnson Sweden; is
8 that right?

9 A. I will not say what the -- that was
10 the right name, but there was a Johnson & Johnson
11 building, with -- you know, taking care of the
12 business, the general management in Scandinavia.

13 Q. It sounds like you're talking about
14 that may have just been an office of the Johnson &
15 Johnson located in Somerville, New Jersey that was
16 over in Scandinavia. Is that your understanding?

17 A. No. My understanding was, you know,
18 Johnson & Johnson is a large company that sells all
19 kind of products. So there was a building hosting
20 all the -- you know, the people working in the
21 different franchise of Johnson & Johnson. So that's
22 why I think it's Johnson & Johnson -- it was called
23 at that time an umbrella company, you know so taking
24 care of all the Johnson & Johnson activity.

25 Q. Prior to the time that you were first
page 459

1 contacted about Prof. Ulmsten and his new technique,
2 was Johnson & Johnson in contact or providing any
3 product to Prof. Ulmsten?

4 A. No. Well, the only contact we have
5 had, you know, Ulmsten wrote to the company about
6 his work. And I found in the dossier that I
7 received letters from 1991.

8 Q. So he had been contacting the company
9 starting in 1991 to try to set up meetings with the
10 company?

11 A. Yeah. To try to interest the company
12 and to get support from the company, but
13 unsuccessfully, let's say.

14 Q. Was the product that he was calling
15 about back in 1991 the same prototype that you
16 talked to him about in 1995 or starting in 1995?

17 A. I don't know. You know, it has been
18 a long trip before he came out with the last
19 version. So I know he had been testing many
20 material, many surgical procedure, many way to put
21 the mesh in place. So he had done a lot of work,
22 but I don't know exactly what he did.

23 Q. And was this article that we're
24 looking at here published after the time that you
25 started visiting with Prof. Ulmsten about Ethicon or

page 460

1 Johnson & Johnson's interest or involvement with the
2 product?

3 A. Well, fortunately, I have my
4 reference. So this article I think was published in
5 1996. And I met him in November 1995. So it's
6 probably, you know, I know ledgering takes about one
7 year or six months. It's probably the same time,
8 you know, so...

9 Q. Were you or anyone from Johnson &
10 Johnson involved in the research that is described
11 in this article?

12 A. I don't think so.

13 Q. Do you think that Johnson & Johnson
14 or Ethicon supported this study that's referred to
15 in any way?

16 A. No, we did not support this study in
17 any way.

18 Q. At the time that this article was
19 published, was the company paying Prof. Ulmsten as a
20 consultant, do you know?

21 A. I don't think so, because we had
22 no -- I think I established a relationship with him,
23 so I would say no. I don't know exactly.

24 Q. Just to be clear, is the answer you
25 don't know as you sit here today whether or not

page 461

1 Prof. Ulmsten was actually being paid as a
2 consultant when this article was first published in
3 the International Urogynecologic Journal in 1996?

4 A. Yeah. I don't know, but I have a
5 strong feeling he was not.

6 Q. Okay.

7 If you go back to the first page, I
8 just have a few questions for you.

0495

1 Q. If you turn to page 4, we referred to
2 this under section W, product means Medscand/Prof.
3 Ulmsten's device. Do you see that?

4 A. Yes.

5 Q. If you will turn to page 7,
6 "Milestone Payments," under section 3.6, it says,
7 "In consideration of Medscand entering into this
8 exclusive License and Supply Agreement, and of
9 Medscand's reaching certain milestones relating to
10 the Products, Johnson & Johnson International shall
11 pay to Medscand the following payments: (a) a
12 payment in the amount of...\$200,000, due within
13 five...business days of the execution of this
14 Agreement;" and, "(b) a payment in the amount of...
15 \$400,000, due on February 28...provided, however,
16 that in the event the Clinical Trials as specified
17 in Exhibit C have not been completed by such date,
18 then such amount shall not be due until" the
19 "completion of the...Trials." Do you see that? Do
20 you see that?

21 A. Yes, yes.

22 Q. So Johnson & Johnson is going to pay
23 Medscand, and actually we know that Prof. Ulmsten is
24 a shareholder in that company, an amount for
25 clinical trials that are completed as of February

0496

1 1997, or if they're not completed then, on the
2 future date. Do you see that?

3 A. Yes.

4 Q. And then if you turn then to Exhibit
5 C, it refers specifically to the clinical trials
6 being referred to. And that's at page 34, and
7 actually, the substance is on 35. Do you see that?

8 A. Sorry. Okay.

9 MR. CARTMELL: Are you there,
10 Christy?

11 MS. JONES: I'm not sure we've got
12 the same copy here.

13 I've got it.

14 THE WITNESS: Page 35.

15 BY MR. CARTMELL:

16 Q. So the agreement refers you to
17 Exhibit C to tell you which clinical trials will be
18 acceptable for the \$400,000 payment; is that right?

19 A. Yes.

20 Q. And it states specifically that, "The
21 results of the clinical trials will be considered
22 acceptable if, first, they do not differ
23 significantly from the results published in the
24 original" Ulmsten "article." Do you see that?

25 A. Yes.

0497

1 Q. And then it gives you specifically
2 the safety and efficacy terms that are acceptable.
3 Right?

4 A. Yes.

5 Q. In other words, with respect, for
6 example, to perioperative complications, bleeding of
7 greater than 300 mils, bladder, I think that should
8 say perforations. Right?

9 A. Yes, yes.

10 Q. Then efficacy, it talks about the
11 terms of efficacy.

12 And then, "Second, long term results
13 (over 1 year from operation) do not show a
14 deterioration rate significantly different from
15 those of the standards sub-urethral slingplasties.
16 It is assumed from 12 to 60 months a small gradual
17 decrease in efficacy of 5% is normal." Right?

18 A. Yes.

19 Q. And then "Third," that "no
20 significant number of unexpected...complications
21 appear at any time in the postoperative course." Do
22 you see that?

23 A. Yes.

24 Q. So this is telling Medscand that if
25 you perform clinical trials and if the results of

0498

1 those clinical trials are not less favorable to the
2 TVT product than Prof. Ulmsten's original article,
3 then we'll pay you \$400,000. Correct?

4 A. Yes.

5 Q. And so essentially, this is an
6 agreement that if Prof. Ulmsten or Medscand, the
7 company that he is a shareholder in, does trials and
8 provides results that are advantageous to the TVT,
9 then they'll get a \$400,000 payment. Right?

10 MS. JONES: Object to the form.

11 THE WITNESS: Look that way, yes